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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,989	12/28/2001	Ronald J. Pettis	7767-177409	4392
32330	7590	01/21/2004	EXAMINER	
VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			WILLIAMS, CATHERINE SERKE	
		ART UNIT		PAPER NUMBER 3763 G
DATE MAILED: 01/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/028,989	PETTIS ET AL.
	Examiner	Art Unit
	Catherine S. Williams	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 October 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 27 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4, 6-26 and 28-68 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group A (related to administration of a substance over not more than 10 minutes) in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

### ***Information Disclosure Statement***

The information disclosure statement filed 10/24/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the foreign patent documents and the other prior art references referred to therein has not been considered.

### ***Claim Objections***

Claim 17 is objected to because of the following informalities: Claim 17 is identical to claim 12 and both depend directly from claim 1. Appropriate correction is required.

Claim 39 is objected to because of the following informalities: Claim 39 is identical to claim 34 and both depend directly from claim 18. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite a "microneedle has an outlet of from 0 to 1 mm". One cannot ascertain if the dimension is referring to the diameter, height or length of the outlet. It is suggested that claim language be added to reference the dimension such as --the microneedle has an outlet of from 0 to 1mm along the length of the needle--.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9, 10-22, 31-40, 44-47, 51, 55-58 and 62-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross (US Pat# 5,527,288). Gross discloses a intradermal drug delivery device that includes administering a substance through a small gauge hollow needle having an outlet with an exposed height of between most preferably .3 to 1.0mm which as disclosed would result in delivery of the substance at a depth of between .3 to 2 mm. See 2:18-21. The diameter of the needle is 0.1-0.2mm. The substances for injection include a variety of

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substances that include peptides, proteins, hormones, insulin, nucleic acids, and hydrophobic and hydrophilic compositions. See 6:59+. As shown in figure 3, the needle is inserted perpendicularly into the skin. Means for actively discharging the drug include an infusion pump. See 2:31-35. Example 1 and 2 disclose an infusion flow rate of 0.1 ml/min. See 10:60+.

Claims 1, 4 , 18 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross (US Pat# 5,800,420). Gross discloses an intradermal drug delivery device that includes administering a substance through a small gauge hollow needle having an outlet with an exposed height of between most preferably .3 to 3.0 mm which as disclosed would result in delivery of the substance at a depth of between .3 to 2 mm. See 10:32-39. The disclosure also indicates that the device can be used to deliver a bolus injection (inherently less than 10 minutes in duration). See 3:29-32.

Claims 18, 23-25, 40 and 48-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Palmer (US Pat# 6,537,242). Palmer discloses an intradermal drug delivery device that includes an array of microneedles that includes at least 6 needles. See figure 5. It is noted that these claims have been given a priority date back to 6/29/2001.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 12-25, 31-47, 53-56, 62-63 of copending Application No. 09/893,746. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both claim intradermal injection with enhanced bioavailability of an injected substance to a patient.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat#s 4,512,767 and 5,925,739 discloses devices analogous in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine S. Williams *CSW*.  
January 12, 2004

*Beth Gil*  
U.S. PATENT AND TRADEMARK OFFICE  
TELEPHONE CENTER 5700